

History A 75-year-old white man, was diagnosed with squamous cell carcinoma of the oropharynx in 3/91. The patient's medical history is significant for squamous cell carcinoma of the tongue (1972). He had undergone radiotherapy to the base of the tongue (11/27/72 to 1/15/73, cobalt therapy, 70 Gy); a complete response had been obtained. After the diagnosis of squamous cell carcinoma of the oropharynx (3/91), he underwent buccopharyngectomy (3/18/91). He relapsed 2.5 years later and underwent parotidectomy and neck dissection (9/15/93) with adjuvant chemotherapy with cisplatin/5-FU (9/15/93) and adjuvant radiotherapy (10/4/93 to 11/12/93, electron therapy, 60 Gy). He relapsed 10 months later and underwent extensive chemotherapy over the course of several years: chemotherapy with cisplatin (9/30/94 to 11/29/94, 1/20/95 to 6/2/95, 1/5/96 to 4/12/96, 10/21/96 to 1/15/97), isotretinoin (9/30/94 to 12/23/96), roferon (9/30/94 to 12/23/96), and 5-FU (1/20/95 to 6/7/95, 1/5/96 to 4/16/96, 10/21/96 to 1/13/97). Nodal resection was also performed (7/10/96). Stable disease was obtained. A biopsy (7/10/96) demonstrated the presence of poorly differentiated squamous cell carcinoma. On 2/25/97, 6 years after the original diagnosis, the patient was screened for study enrollment. Findings included left cervical tumefaction.

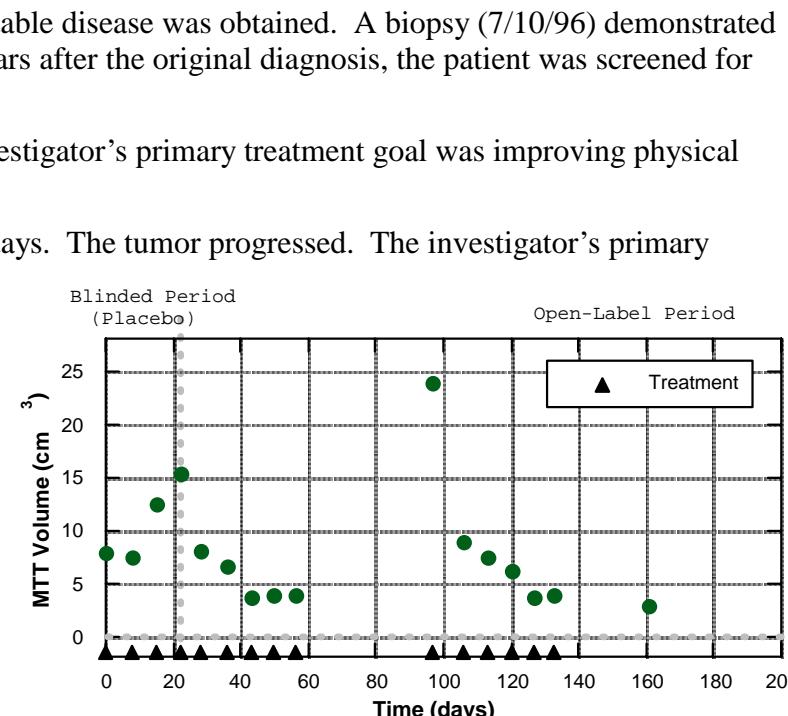
Baseline MTT The MTT (8 cm^3) was cervical, located on the left side. The investigator's primary treatment goal was improving physical appearance and the patient's primary treatment goal was improved wound care.

Blinded Period The patient received 3 placebo treatments to the MTT over 16 days. The tumor progressed. The investigator's primary treatment goal, physical appearance, was not evaluable since the blinded period was less than 28 days, the time needed for treatment goal evaluation. The patient's primary treatment goal, wound care, was not evaluable for the same reason. The patient discontinued the blinded period on Day 23.

Extended Follow-Up Phase This patient received 12 CDDP/epi gel injections over 112 days for treatment of the cervical MTT. An MTT partial response was first observed on Day 92 and lasted for 85 days. The partial response was continuing at the last observation. The patient achieved benefit from CDDP/epi gel treatment: the investigator's primary treatment goal, improvement of physical appearance, was unchanged, but the patient's primary treatment goal of wound care was met for 142 days. Improved wound care was continuing at the last observation. The patient discontinued the extended follow-up on Day 198.

Local Cytotoxic Effects The MTT had no cutaneous effects at baseline or

TREATMENT GROUP		Placebo
	1° Tx GOAL	BLINDED PERIOD OUTCOME
Investigator	Physical appearance	NE
Patient	Wound care	NE
		TUMOR RESPONSE
<i>During the Blinded Period</i>		PD
<i>During Extended Follow-Up</i>		PR
		PATIENT BENEFIT
<i>During the Blinded Period</i>		No
<i>During Extended Follow-Up</i>		Yes



after placebo treatment. During the extended follow-up phase, tumor necrosis peaked at "moderate" on Days 23 and 37; otherwise, the necrosis was graded as "mild" and subsided on study Day 162.

Serious Adverse Events The patient experienced no serious, treatment-related adverse events.

Other Significant Adverse Events There were no severe, treatment-related adverse events.

Other Disease/Intercurrent Illness The patient has a history of left myringoplasty (1968), diabetes mellitus, hypertension, and myocardial infarction.